centervue
at the center of vision

510(k): k101935

OCT 27 2010

# APPENDIX B

## 510(k) Summary of safety and effectiveness

**510(k) OWNER INFORMATION**

| | | |
|---|---|---|
| A. | Company name: | CenterVue SpA |
| B. | Company address: | via Tommaseo 77, 35131, Padova, ITALY |
| C. | Company phone: | +39 049 781 1828 |
| | Company fax: | +39 049 781 1899 |
| D. | Contact person: | Giuliano Barbaro, Managing Director |
| E. | Revised summary date: | September 21st 2010 |

**SUBMITTER INFORMATION**

| | | |
|---|---|---|
| A. | Company name: | Donawa Lifescience Consulting Srl |
| B. | Company address: | Piazza Albania, 10, 00153 Rome, ITALY |
| C. | Company phone: | +39 06 578 2665 |
| D. | Company fax: | +39 06 574 3786 |
| E. | Contact person: | Roger Gray, VP Quality and Regulatory |

**DEVICE IDENTIFICATION**

| | | |
|---|---|---|
| A. | Generic Device name: | Camera, ophthalmic, ac-powered |
| B. | Trade/proprietary name: | Digital Retinography System DRS |
| C. | Classification: | II |
| D. | Product code: | HKI |

**DEVICE DESCRIPTION**

The DRS is an ophthalmic camera used to take colored digital images of a human retina without use of a mydriatic agent. The instrument body includes: optical head, head-rest, chin rest and a base. The device integrates a dedicated computer and a touch-screen display and operates as a standalone unit, running a dedicated software application. The device is provided with a front lens cap, a power cord and spare fuses.

centervue
at the center of vision

## INTENDED USE

The CenterVue Digital Retinography System DRS is intended for taking digital images of a human retina without the use of a mydriatic agent.

## SUBSTANTIAL EQUIVALENCE

The DRS device is substantially equivalent to the following predicate devices with regard to intended use, operating principle, and function:

| Predicate Device | 510(k) Holder | 510(k) No. | Date cleared |
|---|---|---|---|
| EyeScan | Ophthalmic Imaging Systems | K092374 | 17 November 2009 |
| Orion | Nidek Technologies Srl | K070231 | 24 April 2007 |

## TEST DATA

The DRS has undergone extensive performance testing before release to ensure that the device and its software meet the functional requirements and to demonstrate equivalence to the predicate devices.

A summary of the results of performance testing vs. the device requirements follows:

| Performance item | Requirements | Test results |
|---|---|---|
| Sensor resolution | 48 pixels / degree | 48.15 pixels / degree |
| Resolution on retina | ≥ 60 line pairs/mm at the center of the field<br>≥ 40 line pairs/mm at the mid field (r/2)<br>≥ 25line pairs/mm at the periphery of the field (r) | Yes<br>Yes<br>Yes |
| Field of view | 45° horizontal x 40° vertical | 42.95° horizontal x 40.3° vertical |
| Pixel pitch | 6 μm | 6.39 μm |
| Range of focus | -15 D to + 15 D | -15 D to + 15 D |
| Minimum pupil size | 4.0 mm | 4.0 mm |
| Position of internal fixation targets for central and peripheral fields | CENTRAL: field centered on the foveal pit<br>NASAL: field centered 17° nasally to the fovea<br>TEMPORAL: field centered 17° temporally to the fovea<br>SUPERO-TEMPORAL: field centered 12° superiorly and 12° temporally to the fovea<br>PERI-CENTRAL: field centered 5° nasally to the fovea<br>SUPERIOR: field centered 17° superiorly to the fovea<br>INFERIOR: field centered 17° inferiorly to the fovea | Actual position (for normally fixating subjects) within ±1° from expected position |
| OD/OS detection | Device captures OD or OS or both based on operator's selection | Yes (tested on multiple subjects) |
| Auto-alignment | Device automatically aligns to the center of the pupil prior to auto-focusing and capture | Yes (tested on multiple subjects) |

CenterVue SpA
via Tommaseo, 77
35131 Padova, Italy
www.centervue.com
tel. +39 049 781 1828
fax +39 049 781 1899
e-mail: info@centervue.com
REA: 378243 CCIAA PD
C.F./P. IVA: 04296580287

centervue
at the center of vision

**PERFORMANCE STANDARDS**

The DRS complies with the following standards: IEC 60601-1:2005; IEC 60601-1-2:2007; ISO 10940-2:2009; ISO 15004-2 2007.

**CONCLUSION**

As described in this 510(k) Summary, all testing deemed necessary was conducted on the DRS to ensure that the device is safe and effective for its intended use, when used in accordance with its Instructions for Use, and equivalence with the identified predicate devices has been demonstrated.

CenterVue SpA
via Tommaseo, 77
35131 Padova, Italy
www.centervue.com
tel. +39 049 781 1828
fax +39 049 781 1899
e-mail: info@centervue.com
REA: 378243 CCIAA PD
C.F./P. IVA: 04296580287

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

CENTERVUE SpA
c/o Mr. Roger Gray
Vice President, Quality and Regulatory
Donawa Lifescience Consulting Srl
Piazza Albania, 10
00153 Rome, Italy

OCT 27 2010

Re: K101935
Trade/Device Name: Digital Retinography System (DRS)
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: II
Product Code: HKI
Dated: September 29, 2010
Received: October 4, 2010

Dear Mr. Gray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OCT 2 7 2010

# Appendix A

## Indications for Use Statement

**510(k) Number (if known):** K101935

**Device Name:** CenterVue Digital Retinography System DRS

**Indications for Use:** The CenterVue Digital Retinography System DRS is intended for taking digital images of a human retina without the use of a mydriatic agent.

| | | | | |
|---|---|---|---|---|
| Prescription Use (Part 21 CFR 801 Subpart D) | ☒ | AND/OR | Over-The-Counter Use (21 CFR 801 Subpart C) | ☐ |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices



510(k) Number K101935